TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Economic Impact Statement

LSA Document #12-617

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses Description of rule

In 2006, the legislature passed Public Law 155 (now codified as IC 16-19-3-28), which designated the Indiana State Department of Health (ISDH) as the lead agency for the development, implementation, and oversight of a statewide comprehensive trauma system to prevent injuries, save lives, and improve the care and outcome of individuals injured in Indiana. The statute also specified that the ISDH may adopt rules under IC 4-22-2 concerning the development and implementation of a state trauma registry. The trauma registry is a foundational element of the statewide trauma system in that collecting and using data about the performance of the system is the best way to improve the system. This proposed rule provides specific provisions for the development and implementation of the trauma registry.

Economic impact on small businesses

1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.

The proposed rule affects three kinds of small businesses, all in the health care sector: Hospitals that operate emergency departments (EDs), a handful of rehabilitation hospitals, and ambulance (EMS) providers. There are approximately 120 Indiana hospitals operating emergency departments, seven rehabilitation hospitals, and approximately 800 EMS providers in the state. However, only about 18 hospitals are "small businesses" under the definition set out at IC 5-28-2-6, and only about 60 EMS providers qualify as "small businesses" under that same definition.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

The proposed rule will not impose any additional expense on the 60 EMS small businesses, as they are already required to submit exactly the same data set and in the same time frame to the Indiana Department of Homeland Security as proposed in this rule.

The 18 hospitals that qualify as small businesses under this rule will incur some costs in reporting trauma data to the Registry. However, since they are "small businesses", they tend to provide care for a limited number of trauma patients, meaning their reporting burden is fairly low. For example, of the 18 hospitals that fall into the category of "small businesses", none likely care for much more than 100 trauma patients annually.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

All EMS providers already submit to the Indiana Department of Homeland Security the same data set and in the same time frame as specified in the proposed rule, so there is no economic impact on them posed by this rule. Hospital "small businesses" treat a limited number of trauma patients and can reasonably be expected to absorb additional costs into their current operations. Based on calculations from an examination of the hospital discharge database, we believe the total annual economic impact on "small businesses" is less than \$100,000.

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule, and not expressly required by the statute authorizing the agency to adopt the rule, or any other state or federal law.

The proposed rule does not impose additional requirements or costs on small businesses beyond requiring hospitals not now reporting data to the Trauma Registry to do so. A fully functioning trauma system, which includes a trauma registry conducting data-driven performance improvement initiatives, will save millions of dollars annually in health care costs, to say nothing of the lives saved.

Since hospital small businesses treat a limited number of trauma patients, their costs of reporting data about those cases will be limited and can reasonably be expected to be absorbed within the hospital's current operations. EMS small businesses are already required to submit to the Indiana Department of Homeland Security the same data set and within the same time frame as required in this rule, and thus those small businesses will not incur additional costs. It is also fair to note that some hospitals and EMS providers that qualify as "small businesses" will choose not to report data and thus incur additional costs, since there is no significant penalty provided by the rule for failure to report.

5. Regulatory Flexibility Analysis

Other factors considered:

- A. Establishment of less stringent compliance or reporting requirements for small businesses.

 The least stringent means of compliance and reporting requirements have been utilized in this rule. The proposed rule requires hospitals and EMS providers to submit data that they already collect and, in the case of EMS providers, are already required to submit to the Indiana Department of Homeland Security.
- B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

The schedule to report data by EMS providers is the same as they are currently required to report data to the Indiana Department of Homeland Security. The schedule to report data by hospitals matches that required by the National Trauma Data Bank and has been established with the assistance of hospitals that already report data to the Trauma Registry.

- C. Consolidation or simplification of compliance or reporting requirements for small businesses.

 Compliance with the rule will not require any additional action by EMS providers, as they are already required to collect and report the identical data set within the same time frame to the Indiana Department of Homeland Security. In addition, many hospitals already report the required data to the Trauma Registry.
- D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.

The proposed rule requires all hospitals and EMS providers to comply with the same reporting requirements. The proposed Trauma Registry rule is not regulatory in nature. The ISDH has regulatory authority over Indiana hospitals, but the proposed rule will be implemented and overseen by a Department division that does not regulate hospitals. The ISDH has no regulatory role over EMS providers.

E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule. The trauma reporting requirements are intended to increase the amount of data that the ISDH has so that the Department's ability to conduct trauma system performance improvement activities is enhanced. To be able to know whether small hospitals and EMS providers are providing qualify trauma services, all hospital and EMS providers must report data to the Registry.

Conclusion

This proposed rule requires all hospitals and EMS providers to submit trauma data to the Registry. The statewide trauma system needs to collect data to drive its performance improvement initiatives. A fully functioning trauma system that includes a robust trauma registry and effective performance improvement efforts will save millions of dollars in health care costs each year, to say nothing of the lives it will save.

The data that all of these entities must report is data they already have in their possession. EMS providers are not required to submit any more data elements or report them in a different time frame than they are required to report now to the Indiana Department of Homeland Security. The proposed rule will not impose any significant additional expense to the ISDH, the state of Indiana, EMS providers, local government, or hospitals that already report trauma data to the Trauma Registry.

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